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DATE: December 2004 (35.12.2004) U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO.: INTERNATIONAL FILING DATE: PRIORITY DATE CLAIMED: 02 July 2002 (02.07.2002) 02 July 2003 (02.07.2003) PCT/JP2003/008410 TITLE OF INVENTION: CICLESONIDE-CONTAINING STERILE AQUEOUS SUSPENSION APPLICANT(S) FOR DO/EO/US: NISHIBE, Yoshihisa, NAGANO; Atsuhiro, TAKANASHI; Kazuya; UEJIMA, Yasuhide Applicant hereby submits to the Unites States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 2. _ This express request to begin national examination procedures (35 USC 371(f) The submission must include items(5), (6), 3. <u>X</u> (9) and (21) indicated below. A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority 4. <u>X</u> A copy of the International Application as filed (35 U.S.C. 371(c)(2)): 5. X is transmitted herewith (required only if not transmitted by the International Bureau). a. X__ has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US) A English translation of the International Application as filed (35 U.S.C. 371(c)(2). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not transmitted by the International Bureau). have been communicated by the International Bureau. ъ. <u> —</u> have not been made; however, the time limit for making such amendments has NOT expired. . have not been made and will not be made. 8. ___ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. ___ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)) executed in the PCT Request 10. __ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). ITEMS 11 to 20 BELOW CONCERN OTHER DOCUMENT(S) OR INFORMATION INCLUDED: 11. ___ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment A substitute specification. A change of power of attorney and/or address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter2 and 35 USC 1821 - 1825 A second copy of the published international application under 35 USC 154(d)(4) 18. ____ A second copy of the English language translation of the international application under 35 USC 154(d)(4) 19. Other items or information: TRANSMITTAL FORM; FEE CALCULATION; INTERNATIONAL PUBLICATION WO 2004/004739 A1; INTERNATIONAL PUBLICATION DATE 15 JANUARY 2004 WITH SEARCH REPORT WHICH CONSISTING OF 19 PAGES INCLUDING 2 COVER SHEETS CONTAINING THE ABSTRACT; 14 PAGES TEXTUAL SPECIFICATION, 1 PAGE OF 7 CLAIMS, 2 SHEETS DRAWINGS; PRELIMINARY AMENDMENT WITH ATTACHMENT A & B TO BE EXAMINED; UNEXECUTED INVENTOR'S DECLARATION AND POWER OF ATTORNEY; PCT/IPEA/409 INTERNATIONAL PRELIMINARY EXAMINATION REPORT; PCT/IB/304 TRANSMITTAL OF PRIORITY DOCUMENT; PCT/IB/306 NOTIFICATION OF THE RECORDING OF A CHANGE; PCT/IB/308 NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES; PCT/IB332 INFORMATION CONCERNING ELECTED OFFICES

NOTIFIED OF THEIR ELECTION.

U.S. APPLICATION NO.

INTERNATIONAL APPLICATION NO.

DATE; 30 December 2004 30 12.2004)

U.S. APPLICATION NO (if known) not yet assigned 10/519		INTERNATIONAL APPLICATION NO. PCT/JP2003/008410			DATE; 30 December 2004 30 12.2004)		
17. x The following fees are submitted: Basic National Fee (37 CFR 1.492(a)(1)-(5): with Basic Search and Examination fee :\$1,000.00					<u>ULATIONS</u> 1,000.00	PTO USE ONLY	
ENTER APPROPRIATE BASIC FEE AMOUNT =					1,000.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$			
CLAIMS	NO. FILED	NO. EXTRA	RATE				
TOTAL	<u>9</u> -20=	0	X \$ 50.00	\$	0.00		
INDEPENDENT	_2 -3=	0	X \$ 200.00	\$	0.00		
Multiple dependent claims(s) (if applicable) + \$360.00					0.00		
TOTAL OF ABOVE CALCULATIONS =					1,000.00		
Reduction by 2 for asserting small entity, if applicable. (Note 37 CFR 1.9, 1.27, 1.28).					0.00		
SUBTOTAL =					1,000.00		
Processing fee of \$130.00 for furnishing the English translation later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				\$	0.00		
TOTAL NATIONAL STAGE FILING, SEARCH & EXAMINATION FEE =				\$	1,000.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	0.00		
TOTAL FEES ENCLOSED =				 	1,000.00		
				Amoun	it to be: refunded charged	\$	

U.S. APPLICATION NO. (if known) not yet assigned

INTERNATIONAL APPLICATION NO.

DATE: December 2004 (.12.2004)

PCT/JP2003/008410

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a. <u>X</u>	One check in the amount of \$1,000.00 to cover the above fees is enclosed.					
b	Please charge my Deposit Account No. 14-0112 in the amount of \$ to cover the above fees. (A duplicate copy of this sheet is enclosed.)					
c. <u>X</u>	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0112.					
d.	Fees are to be charged to a credit card WARNING: Information on this form may become public Credit Card Information should not be included on this form Provide credit card information and authorization on PTO-2038					
NOTE:	Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed to request that the application be restored to pending status.					
Send All Correspondence To:						
Gary M. Nath NATH & ASSOCIATES PLLC 1030 15 th Street, N.W. Sixth Floor Washington, D.C. 20005						
` ,	75-8383 (phone) 75-8396 (fax) Cary M. Nath Registration Number 26,965 Joshua B. Goldberg					
	Registration Number 44,126					

Sheldon M. McGee Registration No. 50,454 Customer No. 34375

Rev. 02/98

10/519484 MAIL STOP PCT

Docket No. 26430U Attorn D112 Rec'd PCT/PTO 3 0 DEC 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

NISHIBE et al.

International Application No. PCT/JP2003/008410

Serial No. NOT YET ASSIGNED

International Filing Date: 2 July 2003 (02.07.2003)

December 30, 2004 Filed:

For: CICLESONIDE-CONTAINING STERILE AQUEOUS SUSPENSION

TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- Transmittal Letter; (1)
- (2) Application Data Sheet;
- Transmittal Letter To U.S. Designated/Elected Office (DO/EO/US) (3) Concerning Filing under 35 U.S.C. 371;
- International Publication No: WO 2004/004739 A1 (4)International Publication Date: 15 January 2004 (15.01.2004) with Search Report which consists of 19 pages including:
 - 2 cover sheets containing the Abstract,
 - 14 pages Textual Specification,
 - 1 page of 7 claims,
 - 2 sheets of Drawings;
- Preliminary Amendment with Attachment A & B to be examined; (5)
- Unexecuted Inventor's Declaration and Power of Attorney; (6)
- (7)PCT Request;
- (8) PCT/IPEA/409 International Preliminary Examination Report;
- (9) PCT/IB/304 Transmittal of Priority document;
- (10) PCT/IB/306 Notification of the Recording of a Change;
- (11) PCT/IB/308 Notice informing the Applicant of the Communication of the International Application to the Designated Offices;
- (12) PCT/IB/332 Information concerning elected Offices Notified of Their Election;
- \$ 1,000.00 for Basic National Stage Filing, (13) Check No. 22325 Search and Examination Fee;
- (14) Postcard for early notification of serial number.

Respectfully submitted, NATH & ASSOCIATES PLLC

By:

*3*0, 2004 Date: December NATH & ASSOCIATES PLLC 1030th 15TH Street, NW - 6th Floor Washington, D.C. 20005

GMN/JBG/SMM/dd/PCT.NATLphase.TL

Registration No. 26,965 Joshua B. Goldberg Registration No. 44,126 Sheldon M. McGee Registration No. 50,454

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